Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
TRA-008.01	10/696,389
Applicant	
Boni et al.	
Filing Date	**Group Art Unit**
October 29, 2003	1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,849,490	12/15/1998	Schonwetter et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages Etc.)

	AB	International Search Report, PCT/US03/34240 mailed on July 12, 2005.

EXAMINER		DATE CONSIDERED
	Kuhn	3/26/07

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete If Known	
Application Number	10/696,389
Filing Date	October 29, 2003
First Named Inventor	Lawrence T. Boni
Art Unit	1615
Examiner Name	Kishore, G. S.
Attorney Docket Number	TRA-008.01

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-4,451,447	05-29-1984	Kaplan et al.	
	AB*	US-4,767,874	08-30-1988	Shima et al.	
	AC*	US-5,945,122	08-31-1999	Abra et al.	
	AD*	US-5,665,383	09-09-1997	Grinstaff et al.	
	AE*	US-6,090,407	07-18-2000	Knight et al.	
	AF*	US-6,451,784-B1	09-17-2002	Placke et al.	
	AG*	US-6,419,901-B2	07-16-2002	Placke et al.	
	AH*	US-6,147,060	11-14-2000	Zasloff et al.	
	AI*	US-6,440,393-B2	08-27-2002	Waldrep et al.	
	AJ*	US-6,599,912	07-29-2003	Au et al.	
	AK*	US-6,511,676	01-28-2003	Boulikas	
	AL*	US-5,795,589	08-18-1998	Mayer et al.	
	AM*	US-20020187105-A1	12-12-2002	Zou et al.	
	AN*	US-5,049,389	09-17-1991	Radhakrishnan	
	AO*	US-6,045,828	04-04-2000	Bystrom et al.	
	AP*	US-5,875,776	03-02-1999	Vaghefi	
	AQ*	US-5,006,343	04-09-1991	Benson et al.	
	AR*	US-5,000,958	03-19-1991	Fountain et al.	
	AS*	US-4,933,121	06-12-1990	Law et al.	
	AT*	US-5,849,490	12-15-1998	Schonwetter et al.	
	AU*	US-5,320,906	06-14-1994	Eley et al.	
	AV*	US-6,352,996	03-05-2002	Cao et al.	
	AW*	US-20030059375-A1	03-27-2003	Perez-Soler et al.	
	AX*	US-5,459,127	10-17-1995	Felgner et al.	
	AY*	US-4,372,949	02-08-1983	Kodama et al.	
	AZ*	US-4,396,630	08-02-1983	Riedl et al.	
	AA1*	US-4,394,448	07-19-1983	Szoka, Jr. et al.	
	AB1*	US-5,178,876	01-12-1993	Khokhar et al.	
	AC1*	US-5,334,761	08-02-1994	Gebeyehu et al.	
	AD1*	US-4,693,999	09-15-1987	Axelsson et al.	
	AE1*	US-5,543,152	08-06-1996	Webb et al.	
	AF1*	US-5,279,833	01-18-1994	Rose	
	AG1*	US-5,264,618	11-23-1993	Felgner et al.	
	AH1*	US-5,753,613	05-19-1998	Ansell et al.	
	AI1*	US-4,895,719	01-23-1990	Radhakrishnan et al.	
	AJ1*	US-5,077,056	12-31-1991	Bally et al.	
	AK1*	US-5,741,516	04-21-1998	Webb et al.	
	AL1*	US-5,049,388	09-17-1991	Jack V. Knight	
	AM1*	US-5,616,334	04-01-1997	Janoff et al.	
	AN1*	US-5,641,662	06-24-1997	Robert J. Debs	
	AO1*	US-5,756,353	05-26-1998	Debs	
	AP1*	US-6,843,942-A1	01-18-2005	Katinger et al.	
	AQ1*	US-4,895,452	01-23-1990	Yiournas et al.	

Examiner Signature		Date Considered	3/16/07

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 5

Complete If Known	
Application Number	10/696,389
Filing Date	October 29, 2003
First Named Inventor	Lawrence T. Boni
Art Unit	1615
Examiner Name	Kishore, G. S.
Attorney Docket Number	TRA-008.01

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	BA	GB-2145107-A	03-20-1985			
	BB	WO-86/06959	12-04-1986			
	BC	WO-91/16882	11-14-1991			
	BD	WO-96/19199	06-27-1996			
	BE	WO-93/12240	06-24-1993			
	BF	EP-0069307-A	01-12-1983		Abstract	
	BG	WO-00/29103	05-25-2000			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	Niven, Ralph et al., Nebulization of Liposomes. I. Effects of Lipid Composition, Report, pp. 1127-1133.	
	CB	Katare, O.P., et al., Enhanced *in vivo* Performance of Liposomal Indomethacin Derived From Effervescent Granule Based Proliposomes, J. Microencapsulation, 1995, Vol. 12, No. 5, pp. 487-493.	
	CC	Petkowicz, Jozefa, et al., Hypoglycemic Effect of Liposome-Entrapped Insulin Administered by Various Routes into Normal Rats, Pol. J. Pharmacol. Pharm., 1989, 41, pp. 299-304.	
	CD	Comis, "Carboplatin in the Treatment of Non-Small Cell Lung Cancer: a Review," *Oncology*, 1993 Nov.; 50 (2): 37-41. (Abstract)	
	CE	A.Bargoni, R. Cavalli, G.P. Zara, A. Fundaro, O. Caputo, M.R. Gasco (2001) Transmucosal transport of tobramycin incorporated in solid lipid nanoparticles (SLN) after duodenal administration to rats. Part II - Tissue distribution. Pharmacological Research 43(5): 497-502.	
	CF	J. Lagace, M. Dubreuil, S. Montplaisir (1991) Liposome-encapsulated antibiotics: preparation, drug release and antimicrobial activity against Pseudomona aeruginosa. Journal Microencapsulation 8(1): 53-61.	
	CG	L.S. Ramsammy, G.J. Kaloyanides (1988) The effect of gentamicin on the biophysical properties of phosphatidic acid liposomes is influenced by the O-C=O group of the lipid. Biochemistry 27: 8249-8254.	
	CH	C. Dees, R.D. Schultz (1990) The mechanism of enhanced intraphagocytic killing of bacteria by liposomes containing antibiotics. Veterinary Immunology and Immunopathology 24: 135-146.	
	CI	C. Beaulac, S. Sachetelli, J. Lagace (1999) Aerolization of low phase transition temperature liposomal tobramycin as a dry powder in an animal model of chronic pulmonary infection caused by Pseudomonas aeruginosa. Journal Drug Targeting 7(1): 33-41.	
	CJ	J.F. Marier, J.L. Brazier, J. Lavigne, M.P. Ducharme (2003) Liposomal tobramycin against pulmonary infections of Pseudomonas aeruginosa: a pharmacokinetic and efficacy study following single and multiple intratracheal administrations in rats. Journal Antimicrobial Chemotherapy 52: 247-252.	

Examiner Signature		Date Considered	2/26/07

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Sheet 3 of 5

Complete If Known	
Application Number	10/696,389
Filing Date	October 29, 2003
First Named Inventor	Lawrence T. Boni
Art Unit	1615
Examiner Name	Kishore, G. S.
Attorney Docket Number	TRA-008.01

	CK	E.A. Poyner, H.O. Alpar, M.R.W. Brown (1993) Preparation, properties and the effects of free and liposomal tobramycin on siderophore production by Pseudomonas aeruginosa. Journal Antimicrobial Chemotherapy 34: 43-52.	
	CL	A. Omri, M. Ravaoarinoro, M. Poisson (1995) Incorporation, release and in vitro antibacterial activity of liposomal aminoglycosides against Pseudomonas aeruginosa. Journal Antimicrobial Chemotherapy 36: 631-639.	
	CM	C. Beaulac, S. Clement-Major, J. Hawari, J. Lagace (1997) In vitro kinetics of drug release and pulmonary retention of microencapsulated antibiotic in liposomal formulations in relation to the lipid composition. Journal Microencapsulation 14(3): 335-348.	
	CN	P. Demaeyer, E.M. Akodad, E. Gravet, P. Schietecat, J.P. van Vooren, A. Drowart, J.C. Yernault, F.J. Legros (1993) Disposition of liposomal gentamicin following intrabronchial administration in rabbits. Journal Microencapsulation 10(1): 77-88.	
	CO	M. Antos, E.A. Trafny, J. Grzybowski (1995) Antibacterial activity of liposomal amikacin against Pseudomonas aeruginosa in vitro. Pharmacological Research 32(1/2): 84-87.	
	CP	R.M. Schiffelers, G. Storm, I.A.J.M. Bakker-Woudenberg (2001) Therapeutic efficacy of liposomal gentamicin in clinically relevant rat models. International Journal Pharmaceutics 214: 103-105.	
	CQ	L.E. Bermudez, A.O. Yau-Young, J.-P. Lin, J. Cogger, L.S. Young (1999) Treatment of Disseminated Mycobacterium avium Complex Infection of Beige Mice with Liposome-Encapsulated Aminoglycosides. Journal Infect. Dis. 161: 1262-1268.	
	CR	J.H. Zhang and J.B. Zhu (1999) A Novel Method to Prepare Liposomes Containing Amikacin. Journal Microencapsulation 16(4): 511-516.	
	CS	S. Zeng, C. Hu, H. Wei, Y. Lu, Y. Zhang, J. Yang, G. Yun, W. Zou, B. Song (1993) Intravitreal Pharmacokinetics of Liposome-encapsulated Amikacin in a Rabbit Model. Opthamology 100: 1640-1644.	
	CT	M.H. Cynamon, C.E. Swenson, G.S. Palmer, & R.S. Ginsberg (1989) Liposome-Encapsulated-Amikacin Therapy of Mycobacterium avium Complex Infection in Geige Mice. Antimicrobial Agents and Chemotherapy 33(8): 1179-1183.	
	CU	R.M. Fielding, L. Moon-McDermott, R.O. Lewis, M.J. Horner (1999) Pharmacokinetics and Urinary Excretion of Amikacin in Low-Clearance Unilamellar Liposomes after a Single or Repeated Intravenous Administration in the Rhesus Monkey. Antimicrobial Agents and Chemotherapy 43(3): 503-509.	
	CV	K. Yanagihara (2002) Design of anti-bacterial drug and anti-Mycobacterial drug for drug delivery system. Current Pharmaceutical Design 8: 475-482.	
	CW	T.C. Whitehead, A.M. Lovering, L.M. Cropley, P. Wade, R.N. Davidson (1998) Kinetics and Toxicity of Liposomal and Conventional Amikacin in a Patient with Multidrug-Resistant Tuberculosis. Eur J Clin Microbiol Infect Dis 17: 794-797.	
	CX	E. A. Petersen, J.B. Grayson, E.M. Hersh, R.T. Dorr, S.-M. Chiang, M. Oka, R.T. Proffitt (1996) Liposomal amikacin: improved treatment of Mycibacterium avium complex infection in the beige mouse model. Journal Antimicrobial Chemotherapy 38: 819-828.	
	CY	A.A. Roehrborn, J.F. Hansbrough, B. Gauldoni, S. Kim. (1995) Lipid-based slow-release formulation of amikacin sulfate reduces foreign body associated infections in mice. Antimicrobial Agents Chemotherapy 39: 1752-1755.	
	CZ	S.B. Howell (2001) Clinical applications of a novel sustained-release injectable drug delivery system: Depofoam Technology. Cancer Journal 7: 219-227.	
	CA1	A. Omri & M. Ravaoarinoro (1996) Comparison of the Bactericidal Action of Amikacin, Netilmicin and Tobramtcin in Free and Liposomal Formulation against Pseudomonas aeruginosa. Chemotherapy 42: 170-176.	

Examiner Signature		Date Considered	3/16/07

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Sheet 4 of 5

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Filing Date	October 29, 2003
First Named Inventor	Lawrence T. Boni
Art Unit	1615
Examiner Name	Kishore, G. S.
Attorney Docket Number	TRA-008.01

	CB1	L. Kesavalu, J.A. Goldstein, R.J. Debs, N. Duzgunes, P.R.J. Gangadharam (1990) Differential effects of free and liposome encapsulated amikacin on the survival of Mycobacterium avium complex in mouse peritoneal macrophages. Tubercle 71: 215-218.	
	CC1	W.E. Bucke, S. Leitzke, J.E. Diederichs, K. Borner, H. Hahn, S. Ehlers, and R.H. Muller (1997) Surface-Modified Amikacin-Liposomes: Organ Distribution and Interaction with Plasma Proteins. Journal Drug Targeting 5(2): 99-108.	
	CD1	S. Ehlers, W. Bucke, S. Leitzke, L. Fortmann, D. Smith, H. Hansch, H. Hahn, G. Bancroft, and R. Muller (1996) Liposomal amikacin for treatment of M. avium Infections in clinically relevant experimental settings. Zbl. Bakt. 284: 218-231.	
	CE1	E.K. Kim and H.B. Kim (1990) Pharmacokinetics of intravitreally injected liposomes encapsulated tobramycin in normal rabbits. Yonsei Medical Journal 31(4): 308-314.	
	CF1	A. Omri, C. Beaulac, M. Bouhajib, S. Montplaisir, M. Sharkawi, J. Lagace (1994) Pulmonary retention of free and liposome-encapsulated tobramycin after intratracheal administration in uninfected rats and rats infected with Pseudomonas aeruginosa. Antimicrobial Agents and Chemotherapy 38(5) 1090-1095.	
	CG1	J.R. Morgan and K.E. Williams (1980) Preparation and properties of liposome-associated gentamicin. Antimicrobial Agents and Chemotherapy 17(4) 544-548.	
	CH1	P. Lutwyche, C. Cordeiro, D.J. Wiseman, M. St-Louis, M. Uh, M.J. Hope, M.S. Webb, B.B. Finlay (1998) Intracellular delivery and antibacterial activity of gentamicin encapsulated in pH-sensitive liposomes. Antimicrobial Agents and Chemotherapy 42(10) 2511-2520.	
	CI1	R.M. Schiffelers, G. Storm, M.T.T. Kate, L.E.T. Stearne-Cullen, J.G. Den Hollander, H.A. Verbrugh, I.A.J.M. Bakker-Woudenberg (2001) In vivo synergistic interaction of liposome-coencapsulated gentamicin and ceftazidime. Journal Pharmacology Experimental Therapeutics 298(1): 369-375.	
	CJ1	A.I. Vitas, R. Diaz, and C. Gamazo (1996)Effect of composition and method of preparation of liposomes on their stability and interaction with murine monocytes infected with Brucella abortus. Antimicrobial Agents and Chemotherapy 40(1) 146-151.	
	CK1	E.A. Trafny, M. Stepinska, M. Antos, J. Grzybowski (1995) Effects of free and liposome-encapsulated antibiotics on adherence of Pseudomonas aeruginosa to collagen type I. Antimicrobial Agents and Chemotherapy 39(12) 2645-2649.	
	CL1	S.P. Klemens, M.H. Cynamon, C.E. Swenson, R.S. Ginsberg (1990) Liposome-encapsulated-gentamicin therapy of Mycobacterium avium complex infection in beige mice. Antimicrobial Agents and Chemotherapy 34(6) 967-970.	
	CM1	S. D. Nightingale, S.L. Saletan, C.E. Swenson, A.J. Lawrence, D.A. Watson, F.G. Pilkiewicz, E.G. Silverman, S.X. Cal (1993) Liposome-encapsulated gentamicin treatment of Mycobacterium avium-Mycobacterium intracellulare complex bacteremia in AIDS patients. Antimicrobial Agents and Chemotherapy 37(9) 1869-1872.	
	CN1	C.E. Swenson, K.A. Stewart, J.L. Hammett, W.E. Fitzsimmons, R.S. Ginsberg (1990) Pharmacokinetics and in vivo activity of liposome-encapsulated gentamicin. Antimicrobial Agents and Chemotherapy 34(2) 235-240.	
	CO1	I.A.J.M. Bakker-Woudenberg, M.T. ten Kate, L.E.T. Stearne-Cullen, M.C. Woodle (1995) Efficacy of gentamicin or ceftazidine entrapped in liposomes with prolonged blood circulation and enhanced localization in Klebsiella pneumoniae-infected lung tissue. Journal Infectious Diseases 171:938-947.	
	CP1	M.W. Fountain, S.J. Weiss, A.G. Fountain, A. Shen, R.P. Lenk (1985) Treatment of Brucella canis and Brucella abortus in vitro and in vivo by stable plurilamellar vesicle-encapsulated aminoglycosides. Journal Infectious Diseases 152(3): 529-535.	
	CQ1	C.I. Price, J.W. Horton, C.R. Baxter (1992) Liposome delivery of aminoglycosides in burn wounds. Surgery, Gynecology &Obstetrics 174: 414-418.	

Examiner Signature		Date Considered	3/26/07

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	CR1	C.I. Price, J.W. Horton, C.R. Baxter (1994) Liposome encapsulation: a method for enhancing the effectiveness of local antibiotics. Surgery, 115(4): 480-4487.	
	CS1	C.I. Price, J.W. Horton, C.R. Baxter (1989) Enhanced effectiveness of intraperitoneal antibiotics administered via liposomal carrier. Arch Surgery 124: 1411-1415.	

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